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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,709	03/05/2002	Robert G. Gallaher	RNBO-1-1003	7467

7590 03/04/2004

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,709	GALLAHER, ROBERT G.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office is in response to the communication, received 12/12/03, in which applicant withdrew claims 1-13, amended claims 14-20 and added new claims 21-31.

Claims 14-31 are pending.

Claim Rejections - 35 USC § 112

Claims 14-31 stand/are rejected under 35 U.S.C. 112, first paragraph for the reasons set forth in the previous office action which are restated below.

Claims 14-31 stand/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 14-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the topical treatment of Herpes simplex virus type 1 cold sores and Herpes simplex virus type 2 genital lesions via application of taxanes to the skin, does not reasonably provide enablement for the topical treatment of Cytomegalovirus (CMV) and Epstein Barr virus (EBV) via administration of any compounds which target the microtubule process in cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description

of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The invention is drawn to a method to treat viral infection in

mammals, the method comprising: receiving an effective amount of a compostion, taxanes, The viruses targeted are: Herpes simplex virus type 1, Herpes simplex virus type 2, Cytomegalovirus (CMV), and Epstein Barr virus (EBV),

The state of the prior art and the predictability or lack thereof in the art: Based on the teachings of unpredictability regarding *in vivo* therapy which are taught in the prior art, persons skilled in the art would not associate *in vitro* results with *in vivo* therapeutic efficacy. Applicant's specification fails to contain sufficient disclosure to overcome the teachings of unpredictability which are found in the art. *Ex parte Balzarini* 21 USPQ2d 1892 (Bd Pat Appl & Int. 1991). Bernstein (Antiviral Chemotherapy: General Overview, Wright State School of Medicine, Division of Infectious Diseases, 2000) discloses the unpredictability of antivirals for Treatment. Bernstein teaches Acyclovir has been available for the last decade. It was originally released as a topical ointment. Acyclovir was most active against Herpes simplex virus, had some activity against varicella-zoster virus, little activity against Epstein-barr virus and virtually no activity against CMV, see page 1. Disease manifestations of CMV and Epstein-barr virus are usually not on the skin for topical treatment.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The lack of working examples, limited to treating HSV skin lesions using a single extract, for *in vitro* use in the instant specification provide no enablement for *in vitro* use in the treatment of Cytomegalovirus (CMV),and Epstein Barr virus (EBV).

The breadth of the claims and the quantity of experimentation needed: The breadth of the claims, coupled with the quantity of experimentation needed to enable the treatment of Cytomegalovirus (CMV), and Epstein Barr virus (EBV) *in vitro* is deemed excessive.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that in Figure 1 of the instant specification, CMV and EBV are shown to have *in-vitro* activity levels approaching that of HSV-1 and HSV-2. The examiner points out that page 16, lines 1-2 of the instant specification recite "CMV- compounds that have activity in the CPE-inhibition assay were confirmed using the plaque reduction assay in HHF cells." In Figure 1 of the instant application, there is no data entered in the HCMV (HFF cells) under plaque reduction, so it is not possible to compare HSV-1 and HSV-2 *in vitro* activity levels to that of CMV. On page 16, lines 24-26 of the instant specification recite " compounds having good activity against EBV VCA production... will be tested for their ability to inhibit EBV DNA synthesis. In Figure 1 of the instant application, there is no data entered in the EBV DNA section. Applicant's specification fails to contain sufficient disclosure to overcome the teachings of unpredictability which are found in the art. *Ex parte Balzarini* 21 USPQ2d 1892 (Bd Pat Appl & Int. 1991). Bernstein (Antiviral Chemotherapy: General Overview, Wright State School of Medicine, Division of Infectious Diseases, 2000) discloses the unpredictability of antivirals for treatment. Bernstein teaches Acyclovir has been available for the last decade. It was originally released as a topical ointment. Acyclovir was most active against Herpes simplex virus, had some activity against varicella-zoster virus, little activity against Epstein-barr virus and virtually no activity against CMV, see page 1. Disease manifestations of CMV and Epstein-barr virus are

usually not on the skin for topical treatment.

Double Patenting

Claims 14-31 stand/are rejected under the judicially created doctrine of obviousness-type double patenting for the reasons set forth in the previous office action which are restated below.

Claims 14-31 stand/ are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,406,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application, claim 14, is drawn to a method of treating viral infections in mammals, the method comprising: receiving an effective amount of a compostion, taxanes, the effective amount being delivered by a topical route of administration to reduce viral infections in dermal lesions and inflamed areas. Claim 1 of the '722 patent describes a topical method of treating lesions caused by Herpes Simplex Virus 1 (HSV-1), whereby the composition comprises effective amounts of taxane, olive oil and beeswax. Claim 15 of the instant application is drawn to a composition, taxanes. Claims 1, 3, 5, and 7 of the '722 patent describe the use of taxane in the treatment of Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2). Claim 16 of the instant application describe compositions further including solubilizers, lubricants, emulsifiers, waxes, solutions, preservatives, humectants, and analgesics. Claims 1, 3, 5, and 7 of the '722 patent describe the use of beeswax in the composition. Claim 17 of the instant application describes various solutions for use in the composition. Claims 1, 3, 5, and 7

of the '722 patent describe a composition of taxane, olive oil and beeswax. Claim 18 of the instant application describes various solubilizers for use in the composition. Claims 1, 3, 5, and 7 of the '722 patent describe a compostion containing olive oil. Claim 19 of the instant application describes viruses treated with the composition, which include Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2). Claims 1, 3, 5, and 7 of the '722 patent describe the treatment of Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2) with the composition. Claim 20 of the instant application describes a topical route of administration. Claims 2, 4, 6, and 8 of the '722 patent describe a topical route of administration. Thus the claims are considered to be obvious variations (by claim terminology) of the same composition, and not patentably distinct. Absent evidence to the contrary, the composition of the '722 patent is assumed to have the same targeting effect on the microtubule process of mammalian cells as the instant application composition. Claim 21, is drawn to a method of treating viral infections in mammals, the method comprising: receiving an effective amount of a taxane compostion. Claim 1 of the '722 patent describes a topical method of treating lesions caused by Herpes Simplex Virus 1 (HSV-1), whereby the composition comprises effective amounts of taxane, olive oil and beeswax. Claims 1, 3, 5, and 7 of the '722 patent describe the use of taxane in the treatment of Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2). Claims 1, 3, 5, and 7 of the '722 patent describe the treatment of Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2) with the composition. Claims 2, 4, 6, and 8 of the '722 patent describe a topical route of administration. Thus the claims are considered to be obvious variations (by claim terminology) of the same composition, and not patentably distinct. Absent evidence to the contrary, the composition of the '722 patent is assumed to have the same targeting effect on the

microtubule process of mammalian cells as the instant application composition.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the currently amended claims are directed to a broader Herpesviridae group, namely HSV-1, HSV-2, CMV, and EBV. In contrast the Gallaher reference, USPN 6,406,722, is directed to a narrower Herpersviridae group, namely HSV-1 and HSV-2. The instant application, claim 14, is drawn to a method of treating viral infections in mammals, the method comprising: receiving an effective amount of a taxane compostion. Claim 1 of the '722 patent describes a topical method of treating lesions caused by Herpes Simplex Virus 1 (HSV-1), whereby the composition comprises effective amounts of taxane, olive oil and beeswax. Claims 1, 3, 5, and 7 of the '722 patent describe the use of taxane in the treatment of Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2). Claims 2,4,6, and 8 of the '722 patent describe a topical route of administration. Thus the claims are considered to be obvious variations (by claim terminology) of the same composition, and not patentably distinct. Absent evidence to the contrary, the composition of the '722 patent is assumed to have the same targeting effect on the microtubule process of mammalian cells as the instant application composition.

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE
PRIMARY EXAMINER